Expert Report of Laxmaiah Manchikanti, M.D.

1. Background and Qualifications:

I am an anesthesiologist and interventional pain management specialist actively licensed as a physician in Kentucky, Illinois, and Indiana. In 1966 I graduated from Dharmavant Hindi Higher Secondary School, in Hyderabad, India where I obtained my pre-medical education. I then attended Gandhi Medical College at Osmania University in Hyderabad, India from 1966 to 1972 where I obtained my medical degree. From 1972 to 1976, I completed an internship in internal medicine and a residency in anesthesiology at Gandhi Hospital in Secunderabad, India.

From 1977 to 1978, I continued my residency training in anesthesiology with the Department of Anesthesiology at Youngstown Hospital Association at North Eastern Ohio Universities College of Medicine in Youngstown, Ohio, before completing my residency training at Allegheny General Hospital in Pittsburgh, Pennsylvania from 1978 to 1979. Following residency, I completed a fellowship in anesthesiology and critical care medicine at the University of Pittsburgh School of Medicine in Pittsburgh, Pennsylvania from 1979-1980.

I have been certified by the American Society of Anesthesiologists since 1980, with subspecialty certification in Pain Medicine by the American Board of Anesthesiology since 1993. I have also been a Diplomate with the American Board of Pain Medicine since 1993 and a Fellow of the Interventional Pain Practice with The World Institute of Pain since 2002. I am also a Diplomate and Secretary/Treasurer of the American Board of Interventional Pain Physicians.

I have held hospital staff privileges with Lourdes Hospital in Paducah, Kentucky since July of 1980, Western Baptist Hospital in Paducah, Kentucky since February of 1985, Heartland Regional Medical Center in Marion, Illinois since April 2001, Harrisburg Medical Center in Harrisburg, Illinois from July 1988 to 1991, Massac Memorial Hospital in Metropolis, Illinois

from December 1986 to December 1987. In 1985 and 1992, I was also the Director of the Department of Anesthesiology at Lourdes Hospital.

Currently, I am the Medical Director of several pain management facilities, including the Pain Management Center of Paducah, the Ambulatory Surgery Center in Paducah, Kentucky, the Pain Management Center of Marion, and Pain Care Surgery in Marion, Illinois. I am also the founder, Chairman of the Board, and Chief Executive Officer of the American Society of Interventional Pain Physicians (ASIPP), the Society of Interventional Pain Management Surgery Centers (SIPMS), and many state Societies of Interventional Pain Physicians. I also founded the *Pain Physician* Journal, ABIPP, and the ASIPP Foundation.

I have published and served on editorial boards for journals in areas including, but not limited to, pain medicine practice management, pain medicine, interventional pain medicine, interventional techniques in chronic spinal pain, and anesthesiology. I am also a member of a number of professional organizations, including, but not limited to, the American Society of Interventional Pain Physicians, the Kentucky Society of Interventional Pain Physicians, the Illinois Society of Interventional Pain Physicians, the Society of Interventional Pain Management Surgery Centers, and the International Association for the Study of Pain.

A copy of my *curriculum vitae*, more fully setting forth my experience and professional accomplishments, is attached as Exhibit 1. Any publications I have authored in the previous 10 years are listed on my *curriculum vitae*.

2. **List of Cases**

I have testified as an expert in trial or by way of deposition in the past four (4) years in the following case:

> *Jennifer Darlene Bunch and Robert Bunch* vs. Jeffrey Landman, M.D. and Virtual Radiology, PC; Law Office of Barry E. Weathers, Nashville, Tennessee; Case No. 06C-

2495; October 21, 2010; Case went to trial July 2014.

3. Facts and Data Considered in Forming My Opinions:

In forming my opinions, I have generally relied on my education, training, experience, and the materials I have reviewed. The following is a brief summary of the facts I rely upon in forming my opinions regarding Box Hill Surgery Center, LLC, Ritu Bhambhani, M.D., LLC, Ritu T. Bhambhani, M.D., LLC (collectively, "Box Hill Defendants" or "Box Hill"), and any agents or employees of the same.

a. Background for Dr. Bhambhani and Box Hill Surgery Center

Dr. Bhambhani is board certified in anesthesiology and pain medicine. She graduated from medical school in 1994, and then did her post graduate training, including a residency and fellowship in anesthesiology and pain medicine, at the Cleveland Clinic in Ohio. She then obtained her Maryland license and began practicing anesthesiology and pain medicine in Maryland in 2000. She was employed as an anesthesiologist by Harford County Ambulatory Surgery Center (in Maryland) starting in 2003, before opening Box Hill Surgery Center in 2008. Box Hill Surgery Center is a standalone ambulatory surgery center in Abingdon, Harford County, Maryland. Dr. Bhambhani is the sole owner and only regular physician at Box Hill, where she is also the Medical Director. Throughout the years, Dr. Bhambhani has practiced anesthesiology and pain management, including interventional techniques to relieve pain like the ones at issue in this case. In my opinion, Dr. Bhambhani is experienced and well qualified to provide pain management services, among other things. Dr. Bhambhani is also qualified as an anesthesiologist and pain medicine expert to make decisions regarding the purchase of medications for a medical practice.

Box Hill Surgery Center employs a nurse administrator, Andrew Vickers, RN. Mr. Vickers works part time with Dr. Bhambhani to assist her when performing interventional procedures and to assist with administrative functions such as addressing inventory and ensuring that medications, equipment, and other supplies are fully stocked. Mr. Vickers was deposed previously in relation to these cases along with Dr. Bhambhani.

b. Medication Purchasing by the Box Hill Defendants

Dr. Bhambhani began purchasing from NECC on her own in 2008, when she opened Box Hill Surgery Center. Prior to that, she was introduced to NECC's MPA at her previous employer, Harford County Ambulatory Surgery Center, who had also apparently been using NECC's MPA for years. She continued to use it out of a concern for potential adverse events due to preservatives and/or other additives and apparently never experienced any issues with NECC's MPA used at Harford County Ambulatory Surgery Center. As such, she continued to use NECC's preservative free MPA when she opened Box Hill for those therapeutic reasons and because she had not experienced any issues with it.

Box Hill ordered NECC's MPA consistently the same way—through a "Prescription Order Form" provided by NECC. Box Hill placed regular orders with NECC on a routine basis over the years without patient names. NECC was Box Hill's sole supplier of MPA prior to the issues at hand. At some point in 2012, Box Hill was informed by NECC that NECC needed a list of patient names from Box Hill for patients who had or would be receiving a steroid injection. Dr. Bhambhani complied by sending a list of names appearing on the schedule or sometimes the schedule itself. NECC led Box Hill to believe that doing it that way would comply with NECC's requirements.

Again, Box Hill had no problems with NECC's MPA prior to the outbreak issues, and had no reason to believe that the drugs from what was eventually determined to be partially "contaminated lots" were anything but safe.

c. 2012 Meningitis Outbreak and Response

Each of the patients in the instant actions treated by Dr. Bhambhani presented, in most cases, as a referral from another physician, with some sort of back, neck or related pain. Dr. Bhambhani examined each patient, made a diagnosis, and recommended a variety of treatments, including in some instances an interventional procedure with local anesthetic and steroids. Informed consent was obtained and the patient received one or more injections containing preservative-free MPA obtained from NECC.[1]

Dr. Bhambhani first became aware of the outbreak on September 27, 2012, when she received a recall notice from NECC for three different lots of MPA. Dr. Bhambhani complied with the recall notice by quarantining the NECC MPA that she had on hand, and then shipped it back to NECC. In the ensuing weeks and months, Dr. Bhambhani cooperated with the Maryland Department of Health and Mental Hygiene (DHMH), as well as the CDC, by identifying patients who may have received injections from one of the three recalled lots, and by calling each one individually at the request of DHMH and the CDC to make sure they were aware of the risk of developing meningitis or some other infection or adverse event. Dr. Bhambhani followed the instructions of DHMH and the CDC and provided her patients with warning signs to look for and informed them to go to the hospital to be evaluated if they believed they had those symptoms. Dr. Bhambhani also sent out scripted letters as recommended by DHMH and the CDC. Dr.

[1] In some instances, the patients had had previous steroid injections either from Dr. Bhambhani or other physicians. In many cases, those patients had even previously been administered MPA from NECC without complication.

Bhambhani was in continual contact with her patients regarding the recall and outbreak. Many returned to Dr. Bhambhani for treatment.

Although many of Dr. Bhambhani's patients denied suffering any ill effects, some claimed to have suffered from meningitis or other illness and sought hospital care. Four of her patients died, although it is my understanding that there may be some questions as to whether the deaths or other patient claimed illnesses were related to the contaminated steroids from NECC, but that is not a common issue to address at this time. Some of Dr. Bhambhani's patients filed the lawsuits at issue. It is also my understanding that there were some lawsuits filed on behalf of patients that were later dismissed because the patients had not authorized the attorneys to sue Dr. Bhambhani.

4. Materials

I received the materials listed in Exhibit 2, as well as other materials that may be listed within this report, in consideration of forming my opinions. I may review additional materials as appropriate, including any additional depositions taken in this matter. I may review the depositions of the Plaintiffs' Rule 26 witnesses and respond to opinions offered therein. I may review any additional materials identified by the Plaintiffs' Rule 26 witnesses during their depositions and may respond with opinions, if indicated, regarding these materials.

5. Statement of My Opinions Regarding Box Hill:

a. Familiarity with the Standard of Care.

By virtue of my education, training, and experience as an anesthesiologist and interventional pain management physician, I am familiar with the recognized standard of acceptable professional practice ("the standard of care")—what a reasonably prudent health care

provider would do under the same or similar circumstances—applicable to a health care provider purchasing a medication, such as MPA, as that standard existed in 2012.

b. Discussion and Explanation of Medication Purchasing Decisions.

My testimony at trial will include discussion and explanation of medication purchasing decisions including, but not limited to, MPA, from compounding pharmacies and others. I will discuss the factors that go into such decisions, including (1) the consideration given to representations from a compounding pharmacy, (2) consideration given to supply and demand of a particular medication, (3) the role of preservatives in selecting a medication to be used during an epidural steroid injection, (4) the reliance on regulatory authorities such as the FDA and state pharmacy boards to police traditional compounding pharmacies, manufacturers, and entities like NECC, (5) the manner in which medications are ordered from a compounding pharmacy, and (6) the use of patient lists in ordering medications from a compounding pharmacy.

c. Compliance with the Standard of Care

Stated succinctly, I believe it was appropriate and within the standard of care for Box Hill Surgery Center, LLC, Ritu Bhambhani, M.D., and Ritu T. Bhambhani, M.D., LLC. ("Box Hill Defendants") to purchase compounded preservative-free ("PF") methylprednisolone acetate ("MPA") from NECC, including 2012. The following is a more detailed recitation of the factors supporting this opinion. All of my opinions are held to a reasonable degree of medical certainty.

i. The Box Hill Defendants Exercised Appropriate Due Diligence in Purchasing from NECC.

In my expert opinion, the Box Hill Defendants and the involved employees and physician acted within the standard of acceptable practice and exercised appropriate due diligence in selecting NECC as its supplier of MPA. Prior to purchasing from NECC on her own, Dr. Bhambhani had been using NECC's MPA for years at her previous employer with no issues,

according to her deposition. If or when she obtained materials from NECC she saw or would have seen representations by NECC that they were USP <797> compliant, that all medications were formulated by properly licensed pharmacists extensively trained in aseptic compounding, that NECC used only USP quality ingredients in formulating medications, that NECC utilized a state of the art compounding facility and equipment, and that NECC followed a strictly-enforced environmental monitoring program and comprehensive end-product testing program, which included sterility and endotoxin testing by an independent laboratory. Box Hill would have had no reason to question these representations. All are or would have been reassuring to a purchaser of medications and none gave any indication that NECC could not and would not provide safe medications. Additionally, there were no guidelines from any major medical associations recommending any additional due diligence by an ambulatory surgery center prior to purchasing from a medication compounder such as NECC. The absence of any such guidelines, and the fact that the actions by Box Hill were standard practice among ambulatory surgery centers and clinics in 2012, reinforces the propriety of Box Hill's due diligence, prior to purchasing from NECC.

It is also my understanding that depositions by written questions were taken of more than ten other health care providers in Maryland, New Jersey, Tennessee, and elsewhere, to determine if other reasonably prudent health care providers performed any of the due diligence that Plaintiffs allege should have occurred. It is my understanding that none of those entities, including Annapolis Surgery Center, Erlanger Health System, Montclair Orthopedic Group, or Cumberland Valley Surgery Center, among others, engaged in any of it. In other words, all of those entities, and certainly many more across the country, including the Mayo Clinic, Beth Israel Medical Center, Massachusetts General Hospital, and Emory University Hospital, among

others, ordered compounded drugs from NECC in the same manner as Box Hill without doing what Plaintiffs allege was first required.

ii. Box Hill Surgery Center, Ritu Bhambhani, M.D., and Ritu T. Bhambhani, M.D., LLC, complied with the Standard of Care by Purchasing from a Compounding Pharmacy.

It was reasonable for Box Hill to utilize a compounding pharmacy to supply it with MPA, and the standard of care did not require Box Hill to purchase MPA from a drug manufacturer like Pfizer, Teva or Sandoz. There is no standard of care that bars the use of compounding pharmacies like NECC. There was no general belief in the medical community that compounding pharmacies were dangerous. Under the standard of care, compounding pharmacies were an appropriate and acceptable source of medications such as MPA in 2012 and otherwise, and they are still used today. The applicable standard of care does not prohibit a health care provider from purchasing an injectable steroid like MPA from a compounding pharmacy.

Likewise, under the applicable standard of care in 2012, a provider was not required to view compounding pharmacies with any heightened degree of suspicion, or to consider them as a dangerous supplier of medications.

I have reviewed the materials cited by the Plaintiffs as evidence of pre-outbreak reporting on the dangers of compounded medications, including the December 13, 2002 CDC Morbidity and Mortality Weekly Report, the March 24, 2005 USA Today Article entitled "Safety Concerns Grow over Pharmacy-Mixed Drugs," the 2006 Limited FDA Survey of Compounded Drug Products, the 2007 FDA article entitled "The Special Risks of Pharmacy Compounding," the November 5, 2010 Summary Report from the Drug Shortages Summit with the ASHP Report Article entitled "ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health

Systems," a 2010 YouTube video posted by the FDA, and the May 4, 2012 CDC Morbidity and Mortality Weekly Report. The standard of care did not require Box Hill to be aware of this handful of materials before purchasing from NECC. Not one of these materials is from a source typically consulted by providers like Dr. Bhambhani or Mr. Vickers in making medication purchasing decisions at the time that Box Hill purchased from NECC. Further, not one of these articles addresses NECC specifically or suggests that NECC was not a safe supplier of MPA. In my expert opinion, the standard of care did not require the Box Hill Defendants to be aware of these articles at the time they elected to purchase from NECC, or to seek out these articles prior to purchasing from NECC. That simply was not the standard in the profession.

The standard of care did not require Box Hill to purchase MPA from a drug manufacturer. The Plaintiffs suggest that drug manufacturers are safer than compounding pharmacies and that Box Hill should have selected a manufacturer, not a compounding pharmacy, as its supplier of MPA. This suggestion is misleading. Drug manufacturers are not immune from problems concerning the sterility of their manufactured medications and have issued drug recalls on numerous occasions, as indicated in the spreadsheet of drug recalls, which lists product recalls from a multitude of companies, including Pfizer, the well-known supplier of Depo-Medrol (one brand name for MPA). Notably, numerous recalls listed on the spreadsheet were the result of concerns about drug contamination, including the December 20, 2012 dexamethasone sodium phosphate injection recall from American Regent, the February 16, 2012 Cytarabine for injection recall from Bedford Laboratories, the August 14, 2012 propofol injectable emulsion recall from Hospira, Inc., and the February 13, 2014 etomidate injection recall from Pfizer-Mylan, to name only a few. Simply put, purchasing from a drug manufacturer does not provide any guarantee against problems with drug contamination either. There is no

way for a health care provider to ensure that the medication it receives is 100% safe, and buying from an "FDA manufacturer" does not do so. Therefore, it is inaccurate to suggest that the standard of care required Box Hill to purchase from a drug manufacturer, not a compounding pharmacy.

The standard of care did not require Box Hill to purchase brand name MPA (Depo-Medrol) from Pfizer or the generic MPA. Under the standard of care, compounded MPA was a reasonable and acceptable alternative to Depo-Medrol, particularly in light of the fact that Dr. Bhambhani wished to use a preservative free MPA product for therapeutic reasons as indicated in her deposition. Depo-Medrol is not preservative free, and Dr. Bhambhani was reasonably and appropriately interested in procuring preservative free MPA, based on reports of adverse events following epidural steroid injections ("ESIs") with steroids that included preservatives.

iii. NECC's MPA Was a Reasonable Alternative To Depo-Medrol

Compounded MPA was an acceptable alternative to brand name Depo-Medrol. It was reasonable to consider NECC's version of MPA to be like the generic equivalent of Depo-Medrol. Finally, Medicare Part D encourages the use of generic medications. All of these factors support the conclusion that it was reasonable and appropriate for STOPNC to purchase compounded MPA, which is a reasonable equivalent to Depo-Medrol.

iv. The Standard of Care Did Not Require Dr. Bhambhani to be Aware of the FDA and Massachusetts Board of Pharmacy Inspections of NECC.

The standard of care did not require the Box Hill Defendants to be aware of the FDA and Massachusetts Board of Pharmacy inspections of NECC prior to purchasing from it, as none of those reports were published or reasonably or generally available to the public prior to the outbreak. Regardless, the May 24, 2011 Massachusetts Board of Pharmacy inspection report

revealed that NECC was a compliant and safe supplier of medications. Therefore, even if Box Hill had obtained the report prior to purchasing the MPA at issue in 2012, they would have had no reason not to buy from NECC after reviewing the report. The standard of care likewise did not require Box Hill to contact the Massachusetts Board of Pharmacy and/or the FDA regarding NECC prior to purchasing from it or to make any public records request. The Massachusetts Board of Pharmacy offers verification of licensees to the public via its website, which also includes a place for disciplinary actions. Prior to the outbreak, no disciplinary actions were noted for NECC. Accordingly, even if Box Hill had queried the website, it would not have resulted in the discovery of any disciplinary actions. Further, in order to obtain information from the FDA other than what is posted on its website (which, for NECC, was limited to the 2006 warning letter discussed below) a formal request pursuant to the Freedom of Information Act ("FOIA") must be submitted. The standard of care did not require Box Hill to submit any such request. Anecdotally, it is my understanding that a public records request does not provide an instant response. Accordingly, even if such requests had been submitted in the spring or summer prior to placing the orders that resulted in Box Hill receiving the lot(s) eventually recalled, it would not likely have returned timely information.

v. The Standard of Care Did Not Require Dr. Bhambhani and Box Hill to be Aware of the FDA Warning Letter Issued to NECC.

The standard of care did not require Box Hill to be aware of the 2006 FDA warning letter issued to NECC. Under the standard of care, FDA warning letters are not documents that providers like Dr. Bhambhani are required to consider when buying from a drug supplier. The standard of care did not require Dr. Bhambhani or Box Hill to query the FDA for any warnings or actions taken against NECC. Further, the mere fact that a medication supplier has received an FDA warning letter, or even been the subject of an FDA recall, does not preclude the use of that

supplier. To suggest otherwise would inevitably result in the unreasonable exclusion of a large portion of the medication suppliers on the market, including those who are FDA-registered. As noted above, numerous drug manufacturers have been subject to FDA recalls, for a variety of reasons. Moreover, since 2006, FDA warning letters have been issued to both Pfizer and Teva, two FDA-registered manufacturers of MPA. Sandoz, the third FDA-registered manufacturer of MPA, recalled more than 35,000 vials of MPA in 2010. Precluding health care providers from procuring medications from each and every supplier that has ever been subject to an FDA warning or recall would result in an unreasonably narrow list of potential medication suppliers. Consequently, there are no "red flags" (and nothing unique to NECC) that Box Hill should have or would have been aware of that would have caused a reasonable clinic not to buy from NECC.

Even if Dr. Bhambhani had been aware of the 2006 warning letter, it would not have precluded purchasing MPA from NECC under the standard of care, because the warning letter did not pertain to MPA, the product Box Hill purchased from NECC, because the warning letter did not call into question the sterility of NECC's compounded medications, and because the warning letter was about six years old at the time that recalled lots were compounded in 2012, with no public information of further action against NECC by the FDA. In fact, given the fact that NECC was still in operation six years after the letter was issued, it would have been reasonable for Dr. Bhambhani to conclude that the problems triggering the letter had been resolved.

vi. It was Appropriate and in Compliance with the Standard of Care for Box Hill to Rely on the FDA, the Massachusetts Board of Registration in Pharmacy, and/or the Maryland Board of Pharmacy to Regulate NECC.

It was appropriate and in compliance with the standard of care for Box Hill to rely on the FDA, the Massachusetts Board of Registration in Pharmacy, and/or the Maryland Board of

Pharmacy to monitor and regulate NECC and to take action if NECC was utilizing unsafe practices in compounding sterile medications. Based on the fact that NECC was in operation for many years prior and in 2012 with an active, unrestricted license or permit, it was reasonable for Dr. Bhambhani to conclude that it was in compliance with FDA, Massachusetts Board of Registration in Pharmacy, and Maryland Board of Pharmacy regulations, and was operating within safe parameters. Whether or not Dr. Bhambhani checked with the FDA or the Massachusetts or Maryland Boards of Pharmacy to determine if NECC had a valid license is immaterial. It is my understanding that NECC represented to its customers that it possessed such a license, and, in fact, NECC did possess such licenses and permits in those referenced jurisdictions and in nearly every other state across the country. Had Box Hill performed a search it would have found that NECC had such licenses.

vii. The Standard of Care Did Not Require That Box Hill Purchase MPA from an FDA-registered and/or PCAB-accredited Supplier.

The standard of care did not require Box Hill to purchase MPA from a supplier that was registered with the FDA and/or accredited by the Pharmacy Compounding Accreditation Board ("PCAB"). To suggest otherwise is misleading, as neither FDA registration nor PCAB accreditation is a guarantee against contamination problems, as demonstrated by the 2014 and 2015 FDA Inspection Observations of US Compounding, Inc. and the September 2015 US Compounding, Inc. recall. US Compounding, Inc. is a PCAB-accredited and FDA-registered compounding pharmacy. Despite these certifications, in March 2014 and August 2015, inspections by the FDA resulted in multiple criticisms of US Compounding, Inc.'s sterility processes, including the following:

- Failure to wear proper protective apparel to protect against drug contamination (2014);

- Failure to establish procedures designed to prevent microbiological contamination of drug products (2014);

- Failure to maintain buildings used in the manufacture, processing, packing, or holding of drug products in a clean and sanitary condition (2014);

- Failure to employ container closure systems with adequate protection against external factors in storage and use that can cause deterioration or contamination of drug products (2014);

- Failure to utilize appropriate methods of cleaning and disinfecting equipment to produce aseptic conditions (2015);

- Failure to utilize appropriate methods of monitoring environmental conditions in aseptic processing areas (2015);

- Failure to utilize appropriate methods to ensure that air supply is filtered through high-efficiency particulate air filters under positive pressure in aseptic processing areas (2015); and,

- Failure to establish procedures designed to prevent microbiological contamination of drug products purporting to be sterile (2015).

viii. The Standard of Care Did Not Require a Site Visit to NECC.

The standard of care did not require Box Hill to perform a site visit at NECC's facility in Massachusetts. Of the thousands of providers who purchased from NECC, there is no evidence that anything more than a handful performed site visits. This proves that performing a site visit was not "standard." In other words, the standard was to not perform a site visit. In all of my experience purchasing from compounding pharmacies, I have never heard of a provider performing a site visit. It is my understanding that even the entities that may have performed a site visit, like Brigham & Women's Hospital, were hospitals or health system pharmacies, who inspected NECC before deciding to outsource their hospital's own sterile compounding to NECC. Box Hill is a standalone ambulatory surgery center, not a hospital/health system or a pharmacy, and Dr. Bhambhani is not a pharmacist.

Moreover, even if Box Hill had performed a site visit, it is highly unlikely that it would have resulted in any concerns contraindicating purchasing from NECC, for several reasons. First, most clinicians such as Dr. Bhambhani would not know what to look for during a site visit, as they do not have training in compounding processes, clean room design/construction, clean room cleaning, environmental testing, or even ventilation system design/construction. Accordingly, it is unlikely that Dr. Bhambhani or Box Hill would have recognized any concerning issues at NECC's facility, even if one had been present.

Additionally, even if Box Hill had retained an outside entity to conduct a site visit, it is unlikely it would have produced any concerning results. This conclusion is supported by the fact that Brigham & Women's Hospital, in conjunction with Microbiological Research Associates, conducted site visits and audits of NECC in March 2008 and May 2012, both of which resulted in approval of NECC as a supplier of sterile compounded medications to Brigham & Woman's Hospital. The latter inspection is particularly notable, because NECC compounded the first lot of contaminated medications in May 2012, close in time to when the site visit and audit occurred. This conclusion is further supported by the fact that the Massachusetts Board of Registration in Pharmacy conducted an inspection of NECC in May of 2011, which resulted in a finding that NECC appropriately met criteria for ongoing licensure in Massachusetts. Moreover, the Maryland Board of Pharmacy and almost every state board of pharmacy in the United States determined that NECC met their criteria and was fit to have a license/permit to sell drugs in their state for almost a decade before the outbreak. If Brigham & Woman's Hospital, Microbiological Research Associates, the Massachusetts Board of Registration in Pharmacy, and nearly every other state board of pharmacy across the country found no problems with NECC and no reason to restrict, suspend or revoke its license to operate, it is highly unlikely that Box Hill would have

found any. It appears that NECC had SOPs in place and had done the proper air testing. Even if Dr. Bhambhani had decided to inspect SOPs or air testing results at NECC (assuming she even knew what to look for), she likely would have found everything in order, just as the evidence suggests the handful of inspecting customers did.

It is also my understanding, and particularly notable, that Joseph Alessandrini, R.Ph., a pharmacy director at a hospital in New Jersey testified in a common issue deposition on May 13, 2016, that he performed his own due diligence before ordering from NECC, and he also did not find any issues that caused him concern.

ix. The Standard of Care did not Require Investigation into Product Liability Suits against NECC.

The standard of care did not require Box Hill to investigate whether NECC had been the subject of a product liability suit before purchasing from it. Even so, it is my understanding that a single plaintiff had filed a product liability suit against NECC in 2004, more than four years before Box Hill even existed or began ordering from NECC. In comparison, Pfizer, the manufacturer of Depo-Medrol (a brand name of MPA) from whom Plaintiffs claim Box Hill should have been ordering, had been sued by 35,000 plaintiffs around the same time. It is entirely unreasonable to suggest that a health care provider should refrain from purchasing medication from any supplier that had been the subject of a product liability suit. For one, the filing of a lawsuit, as these cases reflect, does not necessarily indicate any actual wrongdoing. Moreover, if Plaintiffs' claims reliance on lawsuits were true, it would result in an unreasonably narrow list of potential medication suppliers (and certainly not Pfizer).

x. The Standard of Care did not Require Dr. Bhambhani to Consult with a Pharmacist.

The standard of care did not require Dr. Bhambhani to consult with a pharmacist prior to making the decision to purchase from NECC. While I personally have chosen to consult at times with a pharmacist at my facilities when purchasing medications that does not mean that the standard of care requires it. In fact, both are acceptable practices. Accordingly, Dr. Bhambhani did not breach the standard of care by not consulting with a pharmacist before ordering medications in her practice including preservative free MPA from NECC.

xi. The Box Hill Defendants Appropriately Considered Medication Supply When Ordering NECC's MPA.

Box Hill acted appropriately and complied with the standard of care by taking into consideration NECC's ability to supply preservative-free MPA when deciding to purchase from NECC. Reducing the risk of adverse events in patients is an appropriate consideration when selecting medication. Dr. Bhambhani reasonably believed that using preservative-free medication would do so, based on reports of adverse events from ESIs using steroids containing preservatives.

Dr. Bhambhani used NECC's MPA because it was preservative free and NECC was able to provide a consistent supply. There is no indication that Dr. Bhambhani considered the price of the MPA in choosing to purchase it from NECC. Nevertheless, even if she did, when purchasing medication from medication suppliers, including pharmaceutical companies and compounding pharmacies, it is appropriate and within the standard of care for a provider to consider the cost of medication and to endeavor to minimize that cost. In fact, medication pricing and the reduction of expenses are factors routinely taken into consideration by providers making medication purchasing decisions. Accordingly, it is appropriate and within the standard of care for a provider making a medication purchasing decision to take into consideration a medication supplier's ability to provide a medication at a lower price than a competitor.

xii. Dr. Bhambhani and the Box Hill Defendants Were Qualified to Make Medication Purchasing Decisions.

Dr. Bhambhani and nurse Andrew Vickers had adequate experience and training under the standard of care and practice to make medication purchasing decisions for Box Hill. First, in my years of experience, I have never heard of any formal training specifically for medication purchasing. As of 2012, Dr. Bhambhani had years of experience making medication purchasing decisions. While nurse Andrew Vickers may have placed some orders and dealt with NECC, Dr. Bhambhani acknowledged in her deposition that she was the one who made the decisions about purchasing. Mr. Vickers followed direction and had been involved in the order and purchase process since about 2008. No additional, specific training in evaluating and purchasing from medication suppliers was required under the standard of care, given their experience level. The fact that Plaintiffs may contend that the Box Hill Defendants had inadequate training concerning ordering and purchasing drugs assumes that it was inappropriate to purchase from NECC, which as detailed in this report, is incorrect.

xiii. The Standard of Care did not Require Additional Policies and Procedures Regarding Medication Purchasing.

The standard of care did not require Box Hill to have any additional policies and procedures in place regarding the purchase of medications, other than those it had. Moreover, criticizing Box Hill for failing to have additional policies and procedures in place regarding the purchase of medications presumes that it was inappropriate for Box Hill to purchase from NECC which, as detailed in my report, is false.

xiv. The Standard of Care did not Require Informing Patients of the use of Compounded MPA.

The standard of care did not require Dr. Bhambhani or the Box Hill Defendants to inform patients that they were receiving compounded MPA during their procedures. Compounded

medication is therapeutically equivalent to a medication manufactured by a drug company. Moreover, there was no reason for Dr. Bhambhani to believe that the compounded MPA presented an increased risk. Furthermore, informing a patient of the identity of each medication used during a procedure, and whether each medication to be administered is a brand name medication, a generic, or a compounded medication was not a standard practice. In my experience, most patients would not appreciate or understand the difference, even if informed that they were receiving generic/compounded MPA versus brand name Depo-Medrol.

xv. NECC's Customer List Demonstrates Purchasing from NECC Complied with the Standard of Care.

In addition to the aforementioned factors, the propriety of Box Hill's decision to purchase medications from NECC is bolstered by the fact that approximately 3,000 other health care providers and facilities, from across the United States, including at least 90 clinics, ambulatory surgical centers, and hospital facilities in Maryland alone, purchased medications from NECC, as reflected by NECC's customer list. That customer list also included such notable facilities as the Emory University Hospital in Atlanta, Durham Regional Hospital at Duke, NYU Medical Center in New York, Brigham and Women's Hospital in Boston, and the University of California San Francisco Medical Center in San Francisco. The mere fact that such a large number and wide array of clinics, ambulatory surgical centers, and hospitals purchased from NECC demonstrates that it was appropriate and in compliance with the standard of care for Box Hill to purchase from NECC.

xvi. Dr. Bhambhani's Uneventful Use of NECC's Compounded MPA Prior to the Outbreak Reinforces the Propriety of the Decision to Purchase from NECC.

In addition to the aforementioned factors, the fact that Dr. Bhambhani had been using NECC"s PF MPA for about a decade before the outbreak without incident reinforces the

propriety of Box Hill's decision to purchase from NECC. Stated another way, based on the fact that Dr. Bhambhani had utilized NECC"s MPA for nearly a decade without incident, it was reasonable for Box Hill to believe, in an ongoing fashion, that NECC was a safe provider of quality MPA, and to continue purchasing from NECC until the outbreak.

xvii. The Standard of Care did not Require Individual Patient Specific Prescriptions.

The standard of care did not require Box Hill to submit individualized, patient-specific prescriptions when purchasing MPA from NECC. It was reasonable for Box Hill to rely on NECC to accurately inform it of the laws and regulations governing purchasing MPA from a compounding pharmacy like NECC, including whether patient-specific prescriptions were required. In fact, for many years, Box Hill bought MPA from NECC by sampling listing the number of vials needed. There was no reason for Box Hill to question NECC's request for lists of patient names, especially since NECC was licensed and approved by state regulatory boards in almost all 50 states. Additionally, the supply of patient names in no way caused any injury to the patients. The same medication would have been sent to Box Hill whether they provided a list of patient names, no patient names, or individual prescriptions. Moreover, it appears that no one was ordering from NECC using actual individual scripts. I have not seen any evidence to show that clinics were ordering from NECC using individualized patient scripts. If thousands of customers of NECC and other supposed compounding pharmacies were ordering drugs without patient specific prescriptions, then that is what defines the standard of care or the standard practice.

xviii. Dr. Bhambhani's Use of "Depo-Medrol" in the Medical Records is Not a Breach of the Standard of Care

Plaintiffs claim that Dr. Bhambhani's use of the term "Depo-Medrol" in the medical records is some sort of negligent or intentional misrepresentation, or that it bears on Dr. Bhambhani's failure to properly obtain her patient's informed consent. Based on my experience and the explanation Dr. Bhambhani provided in her deposition, I disagree. Many physicians are known to use shorthand when authoring their medical records and notes. This instance is no different. It is not unusual to use the brand name that other health care providers may be more familiar with when making notes. In this instance, Depo-Medrol is simply the brand name put on the drug methylprednisolone acetate, when it is manufactured by Pfizer. It is unreasonable to suggest that Dr. Bhambhani's use of "Depo-Medrol" was in any way an attempt to mislead given the widespread use of such shorthand in the medical community. In fact, it is my understanding that an investigator from the Maryland Department of Health and Mental Hygiene used "Solumedrol" when referring to the contaminated drug at issue. Solumedrol is another Pfizer branded injectable steroid, not NECC's preservative-free MPA. Of course she did not intend to suggest that Pfizer's Solumedrol was contaminated. Using Solumedrol was simply her shorthand to make it easier since that is a recognized practice. It is my understanding that a representative of the Maryland Department of Health, Dr. Lucy Wilson, confirmed the same during her deposition and questioning about the same.

Further, informed consent is obtained before the procedure is performed. These notes were drafted after the procedure. According to Dr. Bhambhani's and Mr. Vickers' depositions, Dr. Bhambhani did not tell a patient the brand and chemical formula of the drug that she was going to use in the procedure. She referred to it as a steroid. In my experience, especially as of 2012, in obtaining informed consent, many reasonable physicians did not explain the difference between compounded and commercially manufactured drugs, nor did they describe the specific

chemical name or formula of a drug they were using in a procedure, especially as it related to steroid pain injections. It is my understanding that some of Dr. Bhambhani's patients had even undergone steroid injections prior to the ones that gave rise to these lawsuits, so in many cases they were even already familiar with the process.

In any event, it is my opinion that in using the shorthand "DepoMedrol" or in not informing the patient that she was using a compounded drug versus a commercially manufactured drug, Dr. Bhambhani did not breach the standard of care in the practice of pain medicine.

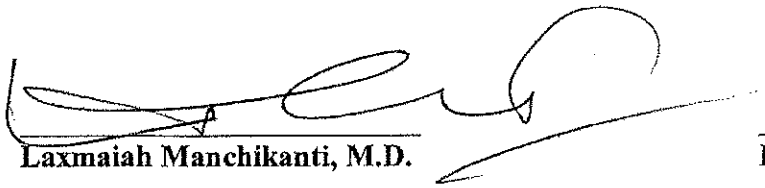
6. Exhibits:

I reserve the right to utilize the documents identified in this report and in Exhibit 2 to summarize or support my opinions, as well as anything produced in discovery. I reserve the right to supplement this report given that discovery is ongoing and because Plaintiffs' experts have yet to be deposed.

7. Compensation:

I charge $500.00 per hour for record review and report preparation and $1,500 for every two hours of deposition plus separate travel and expenses. I also charge $5,000 for a half day of trial and $10,000 for a full day. My compensation is in no way contingent on the outcome of the case.

By:



Laxmaiah Manchikanti, M.D.

10/13/16

Date